

United States Court of Federal Claims

No: 03-234 V

October 5, 2009

FILED UNDER SEAL

**KATHALEEN STAPLEFORD,
Parent of Devon Stapleford,
a Minor,**

Petitioner,

v.

**SECRETARY OF THE DEPARTMENT
OF HEALTH AND HUMAN SERVICES,**

Respondent.

*Ronald C. Homer, Jeffrey S. Thompson, and Thao Da Ho, Conway, Homer & Chin-Caplan,
P.C., Boston, MA, for petitioner.*

*Linda S. Renzi and Gregory W. Fortsch, Vaccine/Torts Branch, Civil Division, United States
Department of Justice, Washington, DC, for respondent.*

OPINION and ORDER

Block, Judge.

I. INTRODUCTION

At 13 months of age, Devon Stapleford received the varicella (chickenpox) vaccine. *Stapleford v. Sec'y of Health & Human Servs.*, No. 03-234, 2009 WL 1456441, at *3 (Sp. Mstr. Fed. Cl. May 1, 2009). Within 24 hours of receiving the vaccine, Devon experienced a seizure. *Id.* During subsequent months, he suffered additional seizures and began to exhibit signs of developmental delay. *Id.* at *3–4. Seizures and developmental problems continue to plague Devon today. *Id.* at *4.

On January 31, 2003, Devon's mother, Kathaleen Stapleford, filed a petition on Devon's behalf, under the National Vaccine Injury Compensation Program (the "Vaccine Act"),¹ claiming that the varicella vaccine caused his seizure disorder. *Id.* After holding an evidentiary hearing on the matter, Special Master George Hastings concluded that no recovery was due because petitioner had failed to demonstrate that the varicella vaccine caused Devon's injury. *Id.* at *5. In addition, the Special Master noted that it was likely a genetic defect, shared by Devon's older brother and unrelated to the vaccine, that caused Devon's medical problems. *Id.* at *14.

Before this court is petitioner's motion for review of the Special Master's decision. Pet'r Mot. for Review at 1. Petitioner's memorandum in support of this motion contains only one numbered objection, namely, that the Special Master applied a standard of proof that is not in accordance with law. Pet'r Mem. at 10. Respondent argues that petitioner's objection amounts to nothing more than a "disagreement with the Special Master's findings and analysis of the evidence." Resp't Mem. at 9. After reviewing the Special Master's decision and the parties' submissions, this court agrees with respondent and sustains the ruling of the Special Master.

II. BACKGROUND

On January 24, 2001, Devon received the varicella and pneumonia vaccines during his 13-month "well-child" visit with his pediatrician. *Stapleford*, 2009 WL 1456441, at *3. The following morning, Devon twice exhibited the symptoms of a seizure, prompting his parents to take him to a hospital emergency room. *Id.* His treating physician concluded that Devon had indeed suffered a seizure, noting a diagnosis of acute seizure disorder. *Id.* The physician discharged Devon later that afternoon, at which time Devon was symptom free. *Id.*

Devon returned to the emergency room three days later after experiencing a grand mal seizure. *Id.* Additional seizures soon followed, prompting the hospital to admit Devon again and place him on anti-seizure medication. *Id.* At this time, the frequency of Devon's seizures ranged from one to three episodes per week. *Id.* at *3-4. Notably, Devon's mother reported that he suffered from seizures the day after he received the diphtheria-tetanus and hemophilus vaccines. *Id.* at *3.

Devon soon began to exhibit signs of developmental delay. In April of 2001, his development was age-appropriate in most areas with a slight delay of less than 25% in the "adaptive" area. Ex. 4 at 126. However, by October of the same year, Devon was "not really speak[ing]" and experiencing "behavioral disturbances." Ex. 4 at 128. By the following year, Devon was exhibiting "complex behavioral problems" similar to autism. Ex. 4 at 32. Devon's neurologist concluded that Devon had "[p]ervasive [d]evelopmental delay." Ex. 5 at 4.

Devon's medical records indicate that he continues to suffer from seizures and developmental problems. *Stapleford*, 2009 WL 1456441, at *4. These records also indicate that his older brother shares similar seizure and developmental problems. *Id.*

¹ 42 U.S.C. §§ 300aa-1 to -34.

On January 31, 2003, Devon's mother filed a petition under the Vaccine Act, seeking compensation on her son's behalf. *Id.* In the petition, she alleges that the January 24, 2001 varicella vaccine caused Devon's seizure disorder. *Id.*

Under the Act, a petitioner may establish a *prima facie* case of causation by one of two methods. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1374 (Fed. Cir. 2009). The first method is relatively simple. If the petitioner can demonstrate that he received a vaccine listed in the Vaccine Injury Table² and that he suffered an injury within the prescribed period of time, then it is presumed that the vaccine caused the injury. *Id.* This is a "table" claim. *Id.*

If the petitioner cannot demonstrate a table claim, then the petitioner must resort to an "off-table" claim. In this second method, the petitioner is not entitled to a presumption of causation. *Walther v. Sec'y of Health & Human Servs.*, 485 F.3d 1146, 1149 (Fed. Cir. 2007). Instead, the petitioner must show by a preponderance of the evidence that the vaccine, in fact, caused the injury. *Id.* In other words, the petitioner must present evidence showing that it was "more likely than not" that the vaccine caused the injury. *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006). In the instant case, petitioner asserts an off-table claim.

In *Althen v. Sec'y of Health & Human Servs.*, the Federal Circuit set forth the following three-prong test for establishing causation in an off-table claim:

Concisely stated, [petitioner's] burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury. If [petitioner] satisfies this burden, she is entitled to recover unless the [respondent] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine.

418 F.3d 1274, 1278 (2005) (internal quotation and citation omitted). Under the first prong, the petitioner must set forth a "reputable medical theory causally connecting the vaccination and the injury." *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355–56 (Fed. Cir. 2006). The inquiry focuses on whether the vaccine in question *can* cause the type of injury alleged. *Id.* at 1356; *Doe 11 v. Sec'y of Health & Human Servs.*, 83 Fed. Cl. 157, 172–73 (Fed. Cl. 2008). By contrast, the second prong focuses on whether the vaccine *did* cause the petitioner's particular injury. *Pafford*, 451 F.3d at 1356; *Nussman v. Sec'y of Health & Human Servs.*, 83 Fed. Cl. 111, 117 (Fed. Cl. 2008). Again, petitioner's theory "must be supported by a 'reputable medical or scientific explanation.'" *Andreu*, 569 F.3d at 1379. Finally, the third prong, "a showing of a proximate temporal relationship," *Althen*, 418 F.3d at 1278, demands more than a simple demonstration that the injury's onset closely followed the vaccine's administration. The petitioner must show that "the onset of symptoms occurred within a timeframe for which, given the medical understanding of the

² The current Vaccine Injury Table can be found at 42 C.F.R. § 100.3.

disorder's etiology, it is medically acceptable to infer causation-in-fact." *De Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2009). Thus, an injury's onset can be too late, *see, e.g., Pafford*, 451 F.3d at 1358, or too early, *see, e.g., De Bazan*, 539 F.3d at 1352, to be properly attributed to the vaccine. Taken together, the three prongs must "cumulatively show that the vaccination was a 'but-for' cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm." *Pafford*, 451 F.3d at 1355.

The transcript of the evidentiary hearing and the Special Master's decision illustrate that Devon's case essentially boiled down to a battle of expert witnesses—Dr. Griesemer for petitioner and Dr. Snodgrass for respondent. Tr. 6; *Stapleford*, 2009 WL 1456441, at *5. Dr. Griesemer recognized that Devon, like his older brother, had a "genetic predisposition to neurodevelopmental problems," Tr. 20, and that absent the varicella vaccine Devon would have likely suffered from seizures and developmental problems, Tr. 27. However, Dr. Griesemer contended that the vaccine caused Devon to suffer seizures earlier in his life than would otherwise have been the case. Tr. 16–17. Dr. Griesemer also testified that but for these early seizures "[Devon's later] seizures . . . would be occasional and could perhaps be problematic, but as equally could be something that could just be watched without medication." Tr. 27. In other words, it was Dr. Griesemer's opinion that the vaccine caused early seizures, which themselves caused additional injury to Devon's brain resulting in a worse developmental outcome for Devon.

Like Dr. Griesemer, Dr. Snodgrass concluded that Devon was genetically prone to seizures and developmental problems. Tr. 48–50. However, unlike Dr. Griesemer, Dr. Snodgrass saw no reason to conclude that the varicella vaccine caused Devon's seizures. Tr. 41–43. Dr. Snodgrass further testified that even if the vaccine triggered Devon's early seizures, the seizures Devon experienced were not of a type or frequency sufficient to have caused or worsened Devon's later developmental problems. Tr. 43–46.

In his decision, the Special Master credited Dr. Snodgrass's testimony over that of Dr. Griesemer and concluded that petitioner had failed all three prongs of the *Althen* test. *Stapleford*, 2009 WL 1456441, at *5, 18, 20. Specifically, the special master ruled that petitioner did not demonstrate by a preponderance of the evidence that the varicella vaccine could cause seizures or that early seizures of the type Devon suffered could worsen a child's developmental outcome. *Id.* at *19. Having concluded that the varicella vaccine *could not* have caused Devon's injury, the Special Master held that the varicella vaccine *did not* cause Devon's injury in this case. *Id.* Thus, petitioner failed the first and second prongs of the *Althen* test.

As to the *Althen* test's third prong, the Special Master noted that Dr. Griesemer "wholly failed to explain at what time frame after vaccination he would *expect* a seizure caused by a varicella vaccination to occur." *Id.* at *20. Accordingly, the special master determined that the "*most striking element*" of petitioner's case—that Devon's first seizure occurred within 24 hours of vaccination—did not establish the requisite "proximate temporal relationship" between the vaccination and Devon's injury. *Id.* at *19–20. In sum, the Special Master concluded that the varicella vaccine did not cause Devon's injury and, therefore, petitioner was not entitled to compensation under the Vaccine Act. *Id.* at *24.

On June 1, 2009, petitioner filed the instant motion for review of the special master's decision. Pet'r Mot. for Review at 1. This court has jurisdiction to consider petitioner's motion pursuant to 42 U.S.C. § 300aa-12(e)(2).

III. DISCUSSION

Upon the motion of a party, this court may review a special master's decision and: (1) uphold the special master's findings of fact and conclusions of law; (2) set aside any of the special master's findings of fact or conclusions of law found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; or (3) remand the petition to the special master for further action in accordance with the court's direction. 42 U.S.C. § 300aa-12(e)(2)(A)–(C); *Broekelschein v. Sec'y of Health & Human Servs.*, No. 07-137, 2009 WL 2569734, *5 (Fed. Cl. Aug. 18, 2009). The findings of fact are reviewed under the highly deferential "arbitrary and capricious" standard and the legal conclusions under the less deferential "not in accordance with law" standard. *Munn v. Sec'y of Health & Human Servs.*, 970 F.2d 863, 870 & n.10 (Fed. Cir. 1992); *Pafford v. Sec'y of Health & Human Servs.*, 64 Fed. Cl. 19, 27 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006).

With regard to a special master's findings of fact, "[i]f the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error [is] extremely difficult to demonstrate." *Hines v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991). Stated another way, the court is "not to second guess the [s]pecial [m]aster's fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process." *Hodges v. Sec'y of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993). This degree of deference is "especially apt" in cases where medical evidence concerning causation is in dispute. *Id.*

Here, petitioner asserts that the Special Master "impermissibly raise[d] the level of scientific proof necessary for a petitioner to prevail in the Vaccine Program." Pet'r Mem. at 11. Petitioner argues:

Instead of considering Devon's strong circumstantial evidence, . . . the [S]pecial [M]aster required "conclusions" by his treating physicians. He required Devon to show a "mechanism" of injury. He required Devon to show that the vaccine "in fact" caused his seizures. He accepted the opinion of the respondent's expert who testified that he needed epidemiology (i.e. scientific certainty) before he would concede that Devon's seizures were caused by his vaccine. To reject Devon's claim, the [S]pecial [M]aster also had to ignore §§ 11 and 13 of the Vaccine Act For him to have done so, . . . was not in accordance with law.

Pet'r Mem. at 11–12. Unfortunately for petitioner, the above arguments are not supported by either fact or law. The court will address each of petitioner's contentions, *seriatim*, below.

Petitioner contends that the Special Master failed to consider Devon's "strong circumstantial evidence," especially the opinions of his treating physicians as recorded in Devon's medical record. Pet'r Mem. at 11, 14–16. However, in his decision, the Special Master went to considerable lengths

to discuss each piece of evidence and why that evidence did or did not support petitioner's case. *See Stapleford*, 2009 WL 1456441, at *6–18. The Special Master paid particular attention to the notations made in Devon's medical record by his treating physicians. *Id.* at *15–18. In eight of these notations, the physician merely restated Devon's uncontested medical history, namely, that his first seizure occurred within 24 hours of receiving the varicella vaccine. Ex. 4 at 69, 101, 110, 137, 141; Ex. 6 at 32, 69, 78. Two of the notations reflect that Devon's parents declined additional vaccinations. Ex. 4 at 13, 126. Two more notations record that Devon's case was reported to the Vaccine Adverse Event Reporting System as a *possible* adverse reaction to a vaccination. Ex. 4 at 8, 93. Finally, in four of the notations, a treating physician explicitly stated that the cause of Devon's seizures is *unknown*. Ex. 4 at 69, 101, 111, 142. The Special Master ultimately concluded that Devon's medical record and the opinion of his physicians contained therein did not provide substantial evidence in favor of petitioner's theory of causation. *Stapleford*, 2009 WL 1456441, at *15.

While this court agrees with petitioner that the medical opinions of treating physicians are “quite probative” when applying the second prong of the *Althen* test, *Capizzano*, 440 F.3d at 1326, this court cannot agree that “[Devon's] treating physicians . . . associated his seizures with the vaccine” Pet'r Mem. at 16. At best, Devon's medical record reflects a general consensus among his physicians that the cause of Devon's seizures is unknown. It was certainly rational for the Special Master to conclude that Devon's medical record did not support petitioner's causation theory.

Next, petitioner complains that the Special Master “required Devon to show a ‘mechanism’ of injury.” Pet'r Mem. at 11. Petitioner correctly cites *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994), for the proposition that a petitioner need not establish a vaccine's mechanism of injury if there is other sufficient evidence proving that the vaccine more likely than not caused petitioner's injury. Pet'r Mem. at 11–12. Yet, in the instant case, the Special Master did not require a mechanism of injury. The Special Master merely noted that petitioner's expert, Dr. Griesemer, did not set forth or even suggest a mechanism by which the vaccine could have harmed Devon's brain. *Stapleford*, 2009 WL 1456441, at *6. Dr. Griesemer admitted that he “[did] not have a specific understanding of the mechanism” and that he is “speculating” when he asserts that “there is a direct impact of the supposedly attenuated [varicella] virus on some population of neurons that . . . infects them in such a way that a seizure occurs” Tr. 19, 33.

Moreover, the few pieces of relevant scientific literature support respondent's expert, not petitioner's. *See Stapleford*, 2009 WL 1456441, at *6–8 (Special Master's discussion of relevant scientific literature). Particularly illuminating is the article entitled *Postmarketing Evaluation of the Safety and Effectiveness of Varicella Vaccine*, which specifically looked for an association between the varicella vaccine and seizures, and found none. Ex. G at 1041, 1044, 1046 (“Seizures were seen during the follow-up periods, but there was no increased risk of this event after [varicella] vaccination when results were adjusted for concomitant administration of other vaccines.”). “Although . . . a claimant need not produce medical literature or epidemiological evidence to establish causation . . . , where such evidence is submitted, the special master can consider it in reaching an informed judgment as to whether a particular vaccination likely caused a particular injury.” *Andreu*, 569 F.3d at 1379 (citing *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 593–97 (1993)). In light of Dr. Griesemer's admittedly speculative medical theory and the lack of evidence supporting it, the Special Master was correct in discounting Dr. Griesemer's testimony. *See Bradley*

v. Sec’y of Health & Human Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993) (holding that special master has broad discretion in determining credibility and reliability of witnesses and ascribing weight to testimony); *Moberly v. Sec’y of Health & Human Servs.*, 85 Fed. Cl. 571, 606 (2009) (holding that special master can consider the reliability and soundness of a party’s proffered biological mechanism theory in support of its causation case); *see also Andreu*, 569 F.3d at 1380 (“The assessment of whether a proffered theory of causation is ‘reputable’ can involve assessment of the relevant scientific data.”).

Petitioner also argues that the Special Master should not have required the petitioner to show that the vaccine, in fact, caused his seizures. Pet’r Mem. at 11. The court is simply dumbfounded by this argument. The Vaccine Act clearly requires any petitioner asserting an off-table claim to show by a preponderance of the evidence that the vaccine caused the petitioner’s injury. 42 U.S.C. § 300aa-13(a)(1)(A), -11(c)(1)(C)(ii). The Federal Circuit has consistently recognized the necessity of establishing causation-in-fact in off-table claims. *E.g.*, *Andreu*, 569 F.3d at 1374; *Walther*, 485 F.3d at 1149; *Capizzano*, 440 F.3d at 1320; *Althen*, 418 F.3d at 1278. The Special Master required nothing more than what the Vaccine Act demands. This court can find no error in this regard.

Petitioner’s last particularized complaint is that the Special Master “accepted the opinion of the respondent’s expert [Dr. Snodgrass] who testified that he needed epidemiology (i.e. scientific certainty) before he would concede that Devon’s seizures were caused by his vaccine.” Pet’r Mem. at 11. Setting aside the fact that the term “epidemiology” is not synonymous with “scientific certainty,”³ the Federal Circuit has emphasized that the appropriate standard of proof for proving causation under the Vaccine Act is a “preponderance of evidence; not scientific certainty.” *Bunting v. Sec’y of Health & Human Servs.*, 931 F.2d 867, 873 (1991). Thus, Dr. Snodgrass’s testimony would be fatally undermined if premised on the notion that he could only offer an opinion that has been conclusively proven within the scientific community.

Once again, petitioner’s argument is not grounded in fact. Dr. Snodgrass merely testified that “[g]iven the information that we have today,” in the absence of an epidemiological study, “[he] would not be able to say that the varicella immunization has increased [children’s] chances of having a seizure.” Tr. 71. As noted above, “the information we have today” indicates that there is no association between the varicella immunization and seizures. Ex. G at 1041, 1044, 1046. At no time did Dr. Snodgrass state or imply that he would need scientific certainty before he would concede that Devon’s seizures were caused by the varicella vaccine. Tr. 38–96.

Moreover, throughout his testimony, Dr. Snodgrass repeatedly recognized that the appropriate inquiry was whether it was probable, i.e., more likely than not, that the varicella vaccine caused Devon’s seizures. Tr. 43–44, 49–50, 86–87, 89. Dr. Snodgrass concluded that such causation was not probable. Tr. 41–46. In sum, there is nothing in the record that supports plaintiff’s contention that Dr. Snodgrass required scientific certainty before he would concede that Devon’s seizures were caused by the varicella vaccine.

³ “Epidemiology” is simply the branch of medical science that “deals with the incidence, distribution, and control of disease in a population.” WEBSTER’S THIRD INT’L DICTIONARY 762 (2002).

Finally, petitioner claims that the Special Master ignored sections 11 and 13 of the Vaccine Act. Pet'r Mem. at 11–12. However, petitioner fails to provide the court with examples of such conduct other than those discussed and dismissed above. The remainder of petitioner's memorandum is devoted to rearguing each prong of the *Althen* test and why, based on the evidence submitted, the Special Master should have found in petitioner's favor. Pet'r Mem. at 16–23. In sum, petitioner essentially asks this court to reweigh the evidence and reach a different conclusion from that of the Special Master. This court respectfully declines. The court has reviewed the Special Master's decision and cannot say that it was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.⁴

IV. CONCLUSION

For the foregoing reasons, the court AFFIRMS the Special Master's decision. The court, accordingly, dismisses the petition with prejudice.

IT IS SO ORDERED.

s/ *Lawrence J. Block*
Lawrence J. Block
Judge

⁴ Indeed, the court believes the Special Master did an admirable job of interpreting and applying the Vaccine Act in light of recent Federal Circuit precedent.